

# Is main operating room sterility really necessary in carpal tunnel surgery? A multicenter prospective study of minor procedure room field sterility surgery

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## Abstract

**Background** Over 70% of Canadian carpal tunnel syndrome (CTS) operations are performed outside of the main operating room (OR) with field sterility and surgeon-administered pure local anesthesia [LeBlanc et al., *Hand* 2 (4):173–8, 14]. Is main OR sterility necessary to avoid infection for this operation? This study evaluates the infection rate in carpal tunnel release (CTR) using minor procedure room field sterility.

**Methods** This is a multicenter prospective study reporting the rate of infection in CTR performed in minor procedure room setting using field sterility. Field sterility means prepping of

the hand with iodine or chlorhexidine, equivalent of a single drape, and a sterile tray with modest instruments. Sterile gloves and masks are used, but surgeons are not gowned. No prophylactic antibiotics are given.

**Results** One thousand five hundred four consecutive CTS cases were collected from January 2008 to January 2010. Six superficial infections were reported and four of those patients received oral antibiotics. No deep postoperative wound infection was encountered, and no patient required admission to hospital, incision and drainage, or intravenous antibiotics.

**Conclusions** A superficial infection rate of 0.4% and a deep infection rate of 0% following CTR using field sterility

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confirm the low incidence of postoperative wound infection using field sterility. This supports the safety and low incidence of postoperative wound infection in CTR using minor procedure field sterility without prophylactic antibiotics. The higher monetary and environmental costs of main OR sterility are not justified on the basis of infection for CTR cases.

**Keywords** Carpal tunnel surgery · Carpal tunnel syndrome · Infection · Field sterility · Local anesthesia · Superficial infection · Deep infection · Main operating room

## Introduction

More than 70% of Canadian carpal tunnel release (CTR) operations are now performed in minor procedure rooms with field sterility under pure local anesthesia, mostly without a tourniquet and with lidocaine with epinephrine [1]. Canadian surgeons feel that this shift from the main operating room to the minor procedure room has increased patient and surgeon convenience, decreased costs, and decreased wait times for surgery, but has not increased wound infection rates. Yet, some centers in the world continue to use traditional main operating room with full sterility for carpal tunnel release with regional or general anesthesia. Likely, this is mostly related to the unknown possibility of increased infection rates with use of minor procedure room field sterility for CTR compared to full room sterility of the main operating theater.

The objective of the study was to accurately record prospectively the risk of infection in performing CTR using minor procedure field sterility. The outcome measure was the postoperative infection rate in a large multicenter series of consecutive patients.

## Methods

The study evaluated prospectively the rate of infection in CTR using surgeon-administered pure local anesthesia in a minor procedure room setting using field sterility by six surgeons in five Canadian teaching centers from January 2008 to January 2010. The outcome measure was the postoperative infection rate. In each center, ethical review board approval and patient consent to participate in the study were obtained. Inclusion criteria were patients who would be good candidates for carpal tunnel release based on both the surgeon's clinical assessment and on nerve conduction studies. Patients were excluded from the study if they were unable to adhere to prescribed follow-up appointments. Postoperative care included at least one visit at between 1 and 2 weeks after surgery. For the purposes of

this study, the time horizon was 2 weeks. It was thought unlikely for patients to suffer infection beyond this time frame. Patients were directed to contact the surgeon if they felt they had an infection. A detailed information sheet was given to patients detailing what to look for with respect to infection and they were provided with specific contact information, so as to be able to contact and alert the attending surgeon or his surgical designate if the patient felt he/she had an infection. The whole process was also explained to the patient verbally when they consented to enter the study. The attending surgeon or his designate examined the patients who felt they were infected and then documented accurately any real infections as defined below and administered appropriate treatment. The infections were determined by the surgical staff and not by emergency room or family doctors.

The definition of a superficial infection for this study was suture abscess or cellulitis of the hand with or without lymphangitis. Deep infection was defined as a wound infection with pus in the depth of the wound that needed incision and drainage or drained spontaneously. The requirement for oral or intravenous antibiotics was recorded.

All CTR cases in this trial were open procedures (non-endoscopic) performed using field sterility in a minor procedure room setting. Minor procedure room means a minor procedure operating room outside of the main operating theater block. These rooms are the same in which minor procedures such as skin cancer excisions are performed. There is no washing of all room structures between cases and no defined airflow control. One nurse serves as circulator and assistant. In this study, field sterility means prepping of the hand with iodine or chlorhexidine, the equivalent of a single 25 × 25 cm drape with a hole in it to expose the palm, and a sterile tray with a modest supply of basic instruments and retractors. Sterile gloves and masks are used, but the surgeons are not gowned or capped. No prophylactic antibiotics are given. All of the surgeons agreed in teleconferences to using the same surgical protocol as well as pre- and postoperative management for the purposes of this study, and this was consistent in all centers and in all patients in the study.

## Results

A total of 1,504 consecutive CTR cases were collected from January 2008 to January 2010. Six surgeons from five Canadian training centers contributed patients to this study. There were 301 patients in Saint John, 1,005 in Ottawa (two surgeons), 75 in Hamilton, 58 in Regina, and 65 in Vancouver. This study did not exclude any patients on the basis of medical comorbidities such as diabetes, steroids,

renal failure, etc. Our patient sample therefore included the normal Canadian distribution of patients with medical comorbidities.

Six superficial infections were reported; four of those six patients received oral antibiotics and two were not severe enough to require antibiotics. Not a single deep postoperative wound infection was encountered. No patient required admission to hospital for a serious infection. No patient received or required an incision and drainage or intravenous antibiotics.

## Discussion

A superficial infection rate of 0.4% and a deep infection rate of 0% following carpal tunnel surgery using field sterility in a minor procedure room outside of the main operating theater block with no prophylactic antibiotics in this study confirm the inherently low incidence of infection and the safety of this approach. This infection rate compares favorably with Hansen's deep infection rate of 0.47% in 3,620 carpal tunnel releases done at their institution in the main operating room [11]. It also compares favorably with Harness' [12] study of 3,003 main operating room CTR patients who had 11 surgical site infections, four deep and seven superficial. Our study supports Harness' conclusion that the routine use of antibiotic prophylaxis in carpal tunnel release surgery is not justified.

No single study in the literature has prospectively looked at infection rates in CTR as a primary outcome. Many papers report on infection as part of their complications of CTR, but few even define their criteria for wound infection and most do not even report on rates of infection as an item in their data. Most studies looking at complications in CTR have reported infection rates of 0% to 6% [3–6, 8–10, 13, 16, 17].

Defining wound infection is very important, as Atherton et al. showed that general practitioners reported infection rates of 14% versus 0% by the specialist hand clinic in a randomized prospective study looking at postoperative follow-up in CTR [1]. We chose the definition of infection described in the method section of this study as it is a practical one, which essentially divides infection into severe (deep infection requiring surgery or intravenous antibiotics) and non-severe (superficial requiring only oral or no antibiotics), simple practical categories understandable to colleague hand surgeons.

The cost of using the main operating theater is more than four times as expensive and only half as efficient as the minor procedure room in carpal tunnel surgery, even without the presence of an anesthesiologist (surgeon-administered local anesthesia) [14]. Office or minor

procedure room CTR with wrist block and wrist tourniquet was evaluated by Derkash et al. and resulted in satisfactory results from CTR, with no significant complications [7]. They also reported that the associated cost of office CTR was approximately 80% of the hospital cost [7].

In spite of the availability of less expensive alternatives, many centers continue to use the main operating room with full sterility for carpal tunnel release with local, regional or general anesthesia, often with the included costs of anesthesiology. Carpal tunnel syndrome incidence in the United States has been estimated at one to three cases per 1,000 persons per year [2]. Prevalence is approximately 50 cases per 1,000 persons in the general population [2]. One million adults are diagnosed with carpal tunnel syndrome each year in the United States [15]. The cost saving which is possible by converting main operating room procedures to minor procedure field sterility and/or deleting the anesthesiology component of this 5–10 min operation is substantial. In addition, for most of the developing world that cannot afford main operating room sterility and/or anesthesiology, this step would put common hand surgery within reach of affordability to many of the planet's poor who now are forced to go without hand surgery.

The reasons for not using wide-awake carpal tunnel release with field sterility include: tradition, reimbursement, inability to re-cooperate tray fees, office availability of instruments, sterilization equipment, and patient preference (the desire for sedation). This paper has provided carefully documented evidence that fear of infection should not be one of these reasons.

We did not separate the patients into risk groups in this study because they are not separated into risk groups in real



**Fig. 1** *Right side* includes disposable materials (waste) from one carpal tunnel syndrome case in the main operating room compared to similar case in the minor procedure room setting on the *left*

clinical practice in most Canadian centers. All patients are treated equally as wide-awake carpal tunnel releases with field sterility in the majority of Canadian centers regardless of their medical comorbidity status. The reason is that this approach takes the operation to the simplicity level of a visit to the dentist. Very few patients are unable to tolerate the minimal pain of the local anesthetic injection without sedation in our experience, and most patients with medical comorbidities are much easier to handle when sedation is taken out of the local anesthetic equation. It is the sedation/general anesthetic component of simple operations that makes stratification into risk groups more important, not the surgery or the location of the surgery.

Figure 1 suggests a possible environmental impact of using main OR sterility. Although we have not studied this in detail, we estimate that the amount of garbage that is generated by main OR sterility is at least ten times that of minor procedure field sterility.

Current economic and environmental needs dictate that we find alternative ways to practice if they do not compromise patient safety. It is important that all surgeons re-examine traditional and “ritualistic” surgical practices and adopt evidence-based approaches to surgery. The evidence from this study confirms that carpal tunnel surgery with surgeon-administered local anesthesia performed in minor procedure room settings with field sterility do not lead to increase in infection rate.

**Conflict of interest** The authors declare that they have no conflict of interest.

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